

REMARKS

This Amendment is submitted in response to the non-final Office Action mailed on July 17, 2007. A petition for a two month extension of time is submitted herewith. The Director is authorized to charge \$460.00 for the petition for extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112843-44 on the account statement.

Claims 1 and 3-25 are pending in this application. Claim 2 was previously canceled. In the Office Action, Claims 17 and 23-25 are rejected under 35 U.S.C. §112, first paragraph, Claims 1, 11, 19-20 and 23 are rejected under 35 U.S.C. §112, second paragraph, Claims 1 and 4-11, 14-20, 22-23 and 25 are rejected under 35 U.S.C. §102 and Claims 1-25 are rejected under 35 U.S.C. §103. In response Claims 1, and 14-16 have been amended and Claims 17 and 23-25 have been canceled without prejudice or disclaimer. These amendments do not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 17 and 23-25 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Patent Office asserts that the specification does not enable one to practice the claimed methods of preventing the recited anandamide mediated ailments and that the specification does not reasonably provide enablement for the prevention of the health problems disclosed in the specification. Applicants respectfully submit that the cancellation of Claims 17 and 23-25 renders moot the rejections under 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 17 and 23-25 under 35 U.S.C. §112, first paragraph, be withdrawn.

In the Office Action, Claims 1, 20 and 23 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the claims describe a moiety "R'" which is not present in the structure depicted in the claims. See, Office Action, page 4, lines 19-23. In response, Applicants have amended Claims 1 and 20 to insert a new chemical structure wherein the R' has been changed to R". Applicants note that the new chemical structure to be entered and having the moiety R" is underlined in both Claims 1 and 20.

Similarly, the previous chemical structure to be deleted and having the moiety R' is double bracketed in both Claims 1 and 20. The double brackets indicate that Applicants wish for the structure having R' to be deleted. Moreover, Applicants note that Claim 23 has been canceled and, therefore, renders moot the rejection of Claim 23 under 35 U.S.C. §112, second paragraph. Based on at least these noted reasons, Applicants believe that Claims 1 and 20 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 20 and 23 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claim 11 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the claim recites "CB receptor," but it is not clear for which receptor the CB stands for. See, Office Action, page 4, lines 24-26. In response, Applicants respectfully submit that the specification clearly sets forth that "anandamide may act as a ligand which interacts with cannabinoid receptors in the central nervous system and gut (CB1 receptors) and/or immune cells and tissues such as spleen, thymus and lymphocytes (CB2)." See, specification, page 4, lines 4-6 (emphasis added). Moreover, the specification also clearly states that "anandamide receptor refers to a receptor that anandamide might bind to, including CB1, CB2, non-CB receptors" and that "anandamide interacts with both the CB1 receptor of the central nervous system and the CB2 receptor of the immune system." See, specification, page 4, lines 14-16, 19-20 (emphasis added). Moreover, there are currently only two known subtypes of cannabinoid receptors, CB1 and CB2, both of which are discussed in the specification. Therefore, Applicants respectfully submit that the skilled artisan would appreciate that "a CB receptor" may refer to either or both of the CB1 and CB2 receptors since the specification clearly states that both CB receptors may react with certain compounds. Based on at least these noted reasons, Applicants believe that Claims 1 and 20 fully comply with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1 and 20 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claim 19 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the claim recites the step of "synthesizing" as a step in a method for "producing" and that since "synthesizing" means

“producing,” the claim is unclear. See, Office Action, page 5, lines 1-4. However, Applicants respectfully disagree with the Patent Office’s statement and submit that the skilled artisan would recognize that the term “synthesis” as used in Claim 19 does not simply means “producing.” Instead, the skilled artisan would recognize that the “synthesizing” of Claim 11 refers to the formation of a chemical compound by combining several simpler compounds or elements through chemical synthesis. Therefore, as used in Claim 11, “synthesizing” comprises a more specific definition than simply “producing.” Moreover, “synthesize” is defined in the chemical sense as “to combine (constituent elements) into a single or unified entity.” See, www.dictionary.com, definition of “synthesize.” As admitted by the Patent Office, the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology. See, Office Action, page 4, lines 12-13. As such, Applicants respectfully submit that a chemically trained Ph.D. and/or M.D. would appreciate the difference between “synthesizing” and “producing.” Based on at least these noted reasons, Applicants believe that Claim 19 fully complies with 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claim 19 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1 and 4-11 are rejected under 35 U.S.C. §102(b) as anticipated by the publication to Di Marzo (“*Di Marzo*”). Claims 1 and 15-17 are rejected under 35 U.S.C. §102(b) as anticipated by the publication to Murillo-Rodriguez et al. (“*Murillo-Rodriguez*”). Claims 1, 5, 14-20, 22-23, and 25 are rejected under 35 U.S.C. §102(b) as anticipated by WO94/28913 to Kyle et al. (“*Kyle*”). In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Currently amended independent Claims 1 and 14-16 recite, in part, a composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 9, lines 6-10. The combination of the naturally occurring precursor and a typical steroid or non-steroidal anti-inflammatory drug (NSAID) provides the advantage that synergy occurs since the combination has the ability to diminish inflammatory via

different pathways. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims.

For example, *Di Marzo*, *Murillo-Rodriguez*, and *Kyle* all fail to disclose or suggest a composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament as required in independent Claims 1 and 14-16. Instead, *Di Marzo* is entirely directed toward a finding that 2-arachidonoyl-glycerol has cannabimimetic activity and may have a role as an "endocannabinoid." See, *Di Marzo*, Abstract. *Murillo-Rodriguez* is directed toward the use of anandamide as well as its precursor metabolite, arachidonic acid, as a sleep and memory modulator. See, *Murillo-Rodriguez*, Abstract. *Kyle* is entirely directed toward methods and pharmaceutical compositions for treating neurological disorders, wherein the compositions include arachidonic acid, docosahexanoic acid or a combination of both. See, *Kyle*, Abstract. Consequently, Applicants respectfully submit that the cited references fail to disclose or suggest a composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament as required in independent Claims 1 and 14-16.

For the reasons discussed above, Applicants respectfully submit that independent Claims 1 and 14-16 and the dependent claims that depend therefrom are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the rejection of Claims 1, 4-11, 14-20, 22-23 and 25 under 35 U.S.C. §102 be withdrawn.

In the Office Action, Claims 1-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Di Marzo* in view of U.S. Patent No. 6,552,031 to Burch et al. ("*Burch*"). Claims 14-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Di Marzo* in view of *Kyle*. In view of the amendments and/or for the reasons set forth below, Applicants believe this rejection is improper and respectfully request that the rejection be withdrawn.

As discussed above, currently amended independent Claims 1 and 14-16 recite, in part, a composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having

anandamide activity for use as a medicament. The combination of the naturally occurring precursor and a typical steroid or non-steroidal anti-inflammatory drug (NSAID) provides the advantage that synergy occurs since the combination has the ability to diminish inflammatory via different pathways.

With respect to Claims 1-13, Applicants respectfully submit that there exists no reason why the skilled artisan would combine *Di Marzo* and *Burch* to arrive at the present claims. For example, because the Patent Office admits that *Di Marzo* does not disclose a combination of an anandamide precursor and an NSAID, the Patent Office cited *Burch* to cure the deficiencies of *Di Marzo*. The Patent Office alleges that *Burch* teaches the combination of oxycodone and rofecoxib. See, Office Action, page 9, lines 16-25. However, Applicants respectfully submit that, in contrast to the Patent Office's assertion, the skilled artisan would have no reason to replace oxycodone with anandamide to arrive at the present claims.

Opioid analgetics, such as oxycodone, may be deployed as a substitute for heroin or morphine, and can result in similar negative side-effects. For example, opioid analgetics can be extremely addictive to the user and can result in adverse reactions including obstipation, respiratory depression, orthostatic hypotension, hallucinations, hyperalgesia, delirium, etc. Oxycodone, in particular, is a controlled substance in the United States both as a single agent and in combination with products containing paracetamol, or ibuprofen or aspirin (NSAIDs). In contrast, the use of an anandamide, a naturally occurring neurotransmitter found in the human body, in conjunction with NSAID's provides the synergistic advantage of the combination without, or with fewer, detrimental side effects than certain drugs, including opioid analgetics. Moreover, opioid analgetics and antimimetics (anandamide) are pharmaceutically different effective groups characterized by different mechanisms of action. Accordingly, Applicants respectfully submit that the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

With respect to Claims 14-25, Applicants respectfully submit that, even if combinable, *Di Marzo* and *Kyle* fail to disclose or suggest every element of the present claims. As discussed previously, *Di Marzo* and *Kyle* fail to disclose or suggest a composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a

medicament as required in independent Claims 1 and 14-16. Instead, *Di Marzo* is entirely directed toward a finding that 2-arachidonoyl-glycerol has cannabimimetic activity and may have a role as an "endocannabinoid," see, *Di Marzo*, Abstract, and *Kyle* is entirely directed toward methods and pharmaceutical compositions for treating neurological disorders, wherein the compositions include arachidonic acid, docosahexanoic acid or a combination of both, see, *Kyle*, Abstract. Specifically, *Kyle* merely specifies the use of non-modified polyunsaturated acids like DHA or ARA. See, *Kyle*, Abstract. For at least the reasons discussed above, the combinations of *Di Marzo* in view of *Burch*, and *Di Marzo* in view of *Kyle* do not teach, suggest, or even disclose the claimed invention, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the obviousness rejection with respect to Claims 1-25 be reconsidered and the rejection be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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